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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,241	01/23/2004	Christopher A. Sikora	3929-5	4510

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,241	SIKORA ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) 7-24 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 23 January 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/6/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-6 and 23) in the reply filed on 8/14/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

NOTE: Claim 23 was erroneously placed in two different Groups (Group I and Group VIII) in the Election Requirement mailed 7/13/06. It's inclusion in Group I was a typographical error as evident in the body of that Restriction Requirement. Accordingly, claim 23 remains in Group VIII and is hereby withdrawn from consideration.

Claims 1-6 are currently under examination. Claims 7-24 are withdrawn from consideration because they are drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not state that the protein has been isolated and/or purified. Accordingly, it reads on a product-of-nature which is non-statutory subject matter.

Claim Rejections - 35 USC § 112-2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it fails to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. The claim provides no structural or functional characteristics which would allow one to identify the protein. The metes and bounds of the invention cannot be understood. Clarification and correction is required.

Claim 1 is also vague and indefinite because it is unclear what is encompassed by synthetic salts medium or weak acidity. What constitutes 'weak acidity"?

Claim 3 is vague and indefinite because it recites a "first infectious agent" and a "second infectious agent" with a high dosage. It is unclear what is encompassed by "infectious agent". What are considered infectious agents? Are they bacterial, viral, etc.? Are the proteins, cells, polysaccharides, etc.? What dosage is considered a "high dosage"? Clarification and correction is required.

Claim 6 is vague and indefinite because it is unclear what is encompassed by "live vaccine strain". What live vaccine strain is this language referring to? Clarification and correction is required.

Claim Rejections - 35 USC § 112-scope of enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an isolated and purified protein from *Francisella tularensis* which has a molecular weight of around 52kDa", does not reasonably provide enablement for "*any* (e.g., any molecular weight or function) subcellular protein expressed from *F.tularensis* infected mammal subculture growing in synthetic salts medium of weak acidity", or "said subcellular protein, wherein said infected mammal is first vaccinated with *any* component extracted from a first infectious agent and then infected with a high dosage of a second infectious agent". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

7. The specification teaches that it was known in the prior art that sera from individuals with infections of tularemia generally do not acquire immunity to the infecting bacteria and that the sera of those vaccinated or infected with F.tularensis has antibodies with affinity for low molecular weight proteins of F.tularensis. These low molecular weight proteins did not appear to give protection when used as vaccines (Golovliov et al. Vaccine. 1995. 15(3): 261-267).

The prior art also taught that the capsule of F.tularensis was not a virulence factor. The prior art also taught that toxins were not present for F.tularensis. Applicants did find that there appeared to be a toxic agent expressed from F.tularensis which had a

delayed action, e.g., 24 hours. Usually, toxins act immediately on host target cells because of their detergent or enzymatic activity. It was by cross-protecting mice against related bacterium, B.abortus, using the O-polysaccharide vaccine which allowed cross-protection against high doses of F.tularemia which would normally kill the mice. The surviving vaccinated mice had antibodies in their sera that recognized the latter bacterial components expressed during the disease process. These antibodies recognized previously overlooked proteins. Applicants identified a 52-kDa protein from this procedure that was specific for F.tularemia. Applicants demonstrated that this specific protein was secreted in synthetic salt medium of weak acidity and were not present when cells were disrupted by sonication to mimic lysis. This appears to signify growth stress, similar to what occurs during the course of normal infection when a bacterium is acquiring metabolites for growth. Tests performed by Applicants demonstrated that the 52kDa protein was toxic virulence factor of F.tularensis. Applicants state on page 37, lines 15-17, that time allowed them only to pursue the 52kDa protein.

The instant claims, 1 and 3-6, are broadly drawn to proteins of any molecular weight. The instant specification has only taught the isolation and characterization of the 52kDa protein from F.tularensis. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting

license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." In the instant case, the specification has only enabled the 52 kDa protein. It would take undue experimentation on the part of the skilled artisan to discover another novel protein from F.tularensis which is a virulence factor and can afford some protection against tularensis.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Golovliov et al (Vaccine. 1995. 15(3): 261-267).

The instant claims are drawn to any subcellular protein express from F.tularensis infected mammal subculture growing in synthetic salts of weak acidity. Golovliov et al teach the isolation of a 17kDa protein from the surface of an agar plate which was infected with F.tularensis which taken from the spleen's of mice that had been infected intraperitoneally with F.tularensis LVS, e.g., lethal dosage of live vaccine strain (claim 6). The spleens were removed and homogenized in sterile saline (salt) and the bacteria

were isolated by incubation at 37 Degrees Celsius for 3 days on modified Thayer-Martin agar. The instant claims fail to define what constitutes "synthetic salts medium of weak acidity". Further, the 17kDA lipoprotein, absent evidence to the contrary, would be expressed under these conditions, as evidenced by the teachings of Golovliov et al. Claims 1 and 3-6 are product-by-process claims. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). In product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

As stated above, claims 1 and 3-6 do not recite any structural properties of the claimed protein and read on proteins from F.tularensis of any molecular weight which have the capability of being expressed in cultures of weak acidity. The prior art teaches that the bacterium becomes more virulent under conditions of weak acidity, e.g., more

proteins are expressed, it is not unreasonable to expect that the 17kDa lipoprotein of Golovliov et al, absent results to the contrary, would be expressed under these conditions. Further, the culture conditions described by Golovliov et al fall under the general description of "synthetic salts medium of weak acidity" recited in the claims.

9. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser
Primary Examiner
Art Unit 1645

10/3/06